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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,450	03/29/2002	Gilbert Gorr	STURK0003	9421

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	

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09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,450	GORR ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3 and 17 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The RCE filed 18 July 2007 is not accepted, because prosecution was not closed. 37 CFR 1.114 provides a procedure under which an applicant may obtain continued examination of an application in which prosecution is closed (e.g., the application is under final rejection or a notice of allowance) by filing a submission and paying a specified fee. See MPEP 706.07(h).

4. The rejection of claims 1-6, 17 and 20-21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the production of secreted proteins in *Physcomitrella patens* by transformation with constructs that encode signal peptides operably linked to the proteins, does not reasonably provide enablement for a method for the production of secreted proteins in other mosses or in liverworts is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 103

5. Claims 1-3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reutter et al (1996, Plant Tiss. Cult. Biotechnol. 2:142-147) in view of Lee et al (US Patent 6,020,169, filed April 1998). The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 January 2007, as applied to claims 1-5, 17 and 19-21. Applicant's arguments filed 18 July 2007 have been fully considered but they are not persuasive.

The claims are drawn to a method of isolating a heterologous protein from culture medium in which in transformed *P. patens* protonema were grown.

Reutter et al teach growth of *P. patens* protonema transformed with a nucleic acid encoding a heterologous protein (pg 143, paragraph 2-3) and that these protonema produced large amounts of the heterologous protein grown in bioreactor culture (pg 143, paragraph 3; Fig. 2-3). Reutter et al also teach that *P. patens* can be grown on inorganic medium (pg 142, paragraph 4). Reutter et al do not disclose isolation of the protein from the culture medium.

Lee et al teach isolation of biologically active heterologous protein from tobacco cells grown in suspension culture. The cells were transformed with a nucleic acid encoding Mab HC operably linked to a mammalian signal peptide (column 12, line 5, to column 19, line 67).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of producing heterologous protein in *P. patens* protonema as taught by Reutter et al, to use a signal peptide in the transformation construct and isolate the protein from media as described in Lee et al. One of ordinary skill in the art would have been motivated to do so because of the advantages of being able to isolate the protein from the medium (Lee et al, column 4, lines 34-54).

Applicant urges that Lee et al describes the isolation of a heterologous protein from tobacco cells, which are known to be permeable to large proteins, citing Raskin; thus, Lee does nothing to show the obviousness of the instant invention (response pg 7).

This is not found persuasive. Raskin indicates that the cell walls are permeable because of the secretion targeting signal on the protein; secretion is the function of secretion targeting signals. This is not something unique to tobacco cells, or even to plant cells.

Applicant urges that mosses are not vascular plants; thus tobacco cells and mosses are not comparable and the combination of Lee with Reutter is not appropriate; Lee does not even consider mosses and liverworts as plants because they are not listed (response pg 7).

This is not found persuasive. Lee shows that collection of heterologous proteins from the media without disruption of cell membranes is within the knowledge and skill of those in the art; it would certainly be obvious for one expressing heterologous proteins in *P. patens, M polymorpha, C. purpureus or F. hygrometica* to try isolating the protein from the medium, given that heterologous proteins could be isolated from the medium in other systems. The lack of vascular systems in mosses is not relevant, as tobacco suspensions cells also do not vascular systems.

Applicant urges that Lee teaches away from the combination because it touts the advantages of suspension cell culture and the instant claims are drawn to intact plants; one of skill in the art would have to assume that intact plants could not secrete into the media (response pg 7).

This is not found persuasive. Lee touts the advantages of suspension cell culture because of the difficulty of growing most whole plant in liquid media; it has nothing whatsoever to do with an assumption that intact plants could not secrete into media. One of skill in the art of transforming and growing mosses and liverworts would know that growing protonema in liquid culture is very possible, as shown by Reutter.

Applicant urges that none of the prior art show secretion of heterologous proteins through the cell wall of photosynthetically active plant tissue without disruption of the cell wall (response pg 8).

This is not found persuasive. Applicant provides no reasons why one of skill in the art would think that photosynthetically active plants could not secrete proteins through the cell wall, when non photosynthetically active plants can.

6. Claims 1-3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reutter et al in view of Lee et al further in view of Nasu et al (1997, J. Ferm. Bioengin. 84:519-523). The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 January 2007, as applied to claims 6 and 21. Applicant's arguments filed 18 July 2007 have been fully considered but they are not persuasive.

The claims are drawn to a method of isolating a heterologous protein from culture medium in which in liverwort protonema were grown.

The teachings of Reutter et al in view of Lee et al are discussed above. Reutter et al in view of Lee et al do not disclose a method of isolating a heterologous protein from culture medium in which in protonema were grown, wherein the protonema were from a liverwort.

Nasu et al teach transformation of *Marchantia polymorpha* (pg 520, left column, paragraphs 1-2). *M. polymorpha* is a photoauxotroph, and thus its growth does not require sugars, vitamins, or phytohormones.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of producing a heterologous protein in protonema tissue as taught by Reutter et al in view of Lee et al, to use liverwort protonema as described in Nasu et al. One of ordinary skill in the art would have been motivated to do so because substitution of one bryophyte for another is an obvious optimization of design parameters. Optimization of parameters is a routine practice that would be obvious for one of ordinary skill in the art to

employ to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the use of *M. polymorpha* would have been obvious at the time of Applicant's invention.

Applicant made no argument specific to this rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
September 19, 2007

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER